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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional): 60117-109

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Application Number	Filed
10/788,606	February 27, 2004

First Named Inventor: Mary E. Brunkow

Art Unit	Examiner
1646	Xiaozhen Xie

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- ☐ applicant/inventor.
- ☐ assignee of record of the entire interest.
  See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
  (Form PTO/SB/96)
- ☒ attorney or agent of record.
  Registration number 33,332
- ☐ attorney or agent acting under 37 CFR 1.34.
  Registration number _____

Signature

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206-628-7650
Telephone number

October 24, 2006
Date

☐ *Total of _____ forms are submitted.

EXPRESS MAIL NO. EV483781997US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	: Mary E. Brunkow et al.
Application No.	: 10/788,606
Filed	: February 27, 2004
For	: ANTIBODIES ASSOCIATED WITH ALTERATIONS IN BONE DENSITY
Examiner	: Xiaozhen Xie
Art Unit	: 1646
Docket No.	: 60117-109
Date	: October 24, 2006

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRE-APPEAL BRIEF REQUEST FOR REVIEW: ARGUMENTS

INTRODUCTORY COMMENTS

Commissioner for Patents:

In response to the Advisory Action dated September 21, 2006, applicants submit these arguments in support of the accompanying Request for a Pre-Appeal Conference.

REMARKS

The Advisory Action dated September 21, 2006, maintained the grounds of rejection of the Office Action dated June 1, 2006. Applicants submit this request for review of the grounds of rejection.

1. The rejection of claims 88-96 under the judicially created doctrine of obviousness-type double patenting over claims 1-8 of U. S. Patent No. 6,803,453, was maintained. Applicants will file a terminal disclaimer upon indication of allowable subject matter in this application.

2. Claims 88-96 were rejected under 35 U.S.C. § 112, first paragraph, for failing to comply with the enablement requirement.

Applicants previously argued that determining whether antigen amino acid substitutions resulting from variations in the polynucleotide sequences of SEQ ID NOs:1, 5, 9, 11, 13 and 15 affect antibody binding would not require undue experimentation. Applicants argued that the specification describes the preparation of antigens as well as the production and testing of antibodies, and that one of skill can routinely identify or construct any antibody molecules meeting the limitations of the claims, and test them for binding to polypeptides encoded by polynucleotides that are at least 90% identical to SEQ ID NOs:1, 5, 9, 11, 13 and 15, or that hybridize to one of those polynucleotides. Applicants further argued that the Bowie et al., Geysen et al., and Colman references support the conclusion that many substitutions in the antigen encoded by polynucleotides having at least 90% identity to SEQ ID NOs:1, 5,9, 11, 13 and 15 are possible without affecting protein folding or antigen binding properties.

The Examiner previously stated that one of skill "would evaluate all non-exemplified TGF-beta binding proteins for antibody binding activity," (Office Action of June 1, 2006, page 5, lines 6-8), which is not a legal requirement. *In re Wands* (8 U.S.P.Q.2d 1400, Fed. Cir. 1988) does not suggest that one of skill would make every single possible antibody within the scope of the claims. Instead, the Court held that it would not require undue experimentation to "obtain antibodies needed to practice the claimed invention." (8 U.S.P.Q.2d at 1406.) *Wands* does not support or require the Examiner's interpretation that one would evaluate all non-exemplified TGF-β binding proteins. By analogy to *Wands*, enablement in the present case is met by the provision

of the starting polynucleotide sequences (SEQ ID NO:1, 5, 9, 11, 13 or 15) and methods of hybridizing other sequences and expressing the TGF-β binding protein.

In the Advisory Action, the Examiner now states that "one of skill has to evaluate any non-exemplified antibody for binding specificity." Applicants submit that testing non-exemplified antibodies is exactly what is permitted under *Wands*. In the Advisory Action, the Examiner did not reiterate his previous statement that "one of skill would evaluate all non-exemplified TGF-beta binding proteins for antibody activity." By now stating "any" non-exemplified antibody, the testing is clearly permissible under case law. The Examiner gave no reasons for changing how he characterized the testing required ("all" versus "any"), so applicants have no guidance on how to overcome this rejection.

3. Claims 88-96 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

In the Advisory Action, the Examiner stated that "without teachings that define any structural features commonly possessed by members of the genus" one of skill cannot "recognize the identity of members of the genus." Applicants respectfully disagree, because the genus is clear from the claims: antibodies that bind to a TGF-ß binding protein encoded by a clearly circumscribed family of polynucleotides.

Applicants respectfully submit again that the class of polynucleotides encoding TGF-ß binding protein is readily determinable based on provision of SEQ ID NOs:1, 5, 9, 11, 13, and 15 under *Falkner v. Inglis*, Slip Op. 05-1324 (May 26, 2006, and errata, July 6, 2006) the application need not disclose the chemical structures. To list the complementary sequences would add "unnecessary bulk" to the application, a practice that *Falkner* rejects.

Applicants again draw attention to U.S. Patent No. 6,562,949, issued on May 13, 2003, in which claim 1 reads as follows:

> 1. An antibody that specifically binds polypeptide with an amino acid sequence that is at least 90% identical to the amino acid sequence of SEQ ID NO:2, wherein the percent identity is calculated using the GAP program with an unary comparison matrix, a 3.0 gap penalty, an additional 0.10 penalty for each symbol in each gap, and no penalty for end gaps, and said polypeptide binds a semaphorin selected from the group consisting of A39 semaphorin and AHV semaphorin.

Applicants submit that this claim language is comparable to the claim language under consideration in the present application. The percent identity in the claim quoted above relates to an amino acid sequence whereas the percent identity of applicants' claims is expressed in terms of the encoding polynucleotide. The 6,562,949 patent issued before the *Falkner* decision, yet appears to be consistent with the holding of that decision.

Applicants request this Review to address the rejections under 35 U.S.C. § 112, first paragraph, enablement, and 35 U.S.C. § 112, first paragraph, written description, with particular attention to the written description standards for an antibody as applied in the present case and in an issued patent. Although each patent application is examined on its own merits, applicants must be able to rely to the same extent on issued claim language for guidance as to interpretation of the rules and the law.

Respectfully submitted,
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